

## **ISLET CELL RESOURCE (ICR) CENTERS**

<http://www.infosci.coh.org/icr>

### **Description of Project**

Some patients with type 1 diabetes mellitus have achieved long-term independence from exogenous insulin after receiving human pancreatic islet cell transplants. Ten Islet Cell Resource Centers (ICRs) were established in September 2001 to expand upon this observation by serving as regional centers that would both provide clinical grade human islets to investigators engaged in islet transplantation protocols throughout the country and optimize the procedures used to obtain such islets.

The mission is to:

- Generate and distribute current Good Manufacturing Practice (cGMP)-grade human pancreatic islets to clinical investigators for transplantation into patients having severe type 1 diabetes mellitus.
- Optimize the processes by which the islets are isolated, purified, characterized, stored, and shipped for use in transplantation protocols.

### **Accomplishments**

- All 10 ICRs have completed an outside audit for compliance with FDA cGMP guidelines.
- A Policy and Procedures document was written and approved by the Steering Committee and funding entities.
- Ninety-two batches of isolated islets have been infused into 47 patients.
- Administrative and Bioinformatics Coordinating Center (ABCC) activities began August 1, 2002.
- The ICR consortium has been described on the NCRR website and in one journal article, while multiple verbal and poster presentations have been made at national meetings.
- A web-based process for data sharing between the ABCC and the NIDDK-supported Collaborative Islet Transplant Registry (CITR) has been established. The ABCC will collect islet generation data and merge the CITR clinical data to enable the development of preparative algorithms predictive of clinical outcome.

### **Future directions**

- Facilitate the placement of pancreata for islet transplantation throughout the U.S.
- Acquire increased numbers of pancreata and distribute islets to more approved clinical transplantation protocols both within and outside of ICR-affiliated institutions.
- Continue efforts to optimize the process by which larger numbers of clinically useful islets reach investigators for use in their protocols throughout the U.S.
- Centralize the process for acquisition and payment for ICR pancreata through the ABCC.

- Participate in national efforts to decrease the unnecessary loss of pancreata that could have been used in transplantation protocols.
- Make Organ Procurement Organizations (OPOs) more aware of the ICR program.

**Materials to be made available to researchers**

- Requests for islets to be used in clinical transplantation protocols at both ICR- and non-ICR-affiliated institutions are reviewed semi-annually by the ICR Steering Committee.
- Islets that are not used in clinical protocols will be made available to investigators engaged in basic research studies.
- Requests for islets to be used in basic research studies are reviewed monthly.

For more information, please visit the ICR website at <http://www.infosci.coh.org/icr>.

**Participants**

Sponsors: National Center for Research Resources  
National Institute of Diabetes and Digestive and Kidney Diseases

Participating Institutions

Each ICR listed below possesses significant expertise in human pancreatic islet isolation and operates a cell processing facility that is compliant with FDA guidelines for cGMP:

University of Miami  
University of Minnesota  
Washington University  
City of Hope/Beckman Research Institute  
Columbia University  
Joslin Diabetes Center  
University of Tennessee  
Puget Sound Blood Center  
University of Colorado  
University of Pennsylvania

Steering Committee

<u>Name</u>	<u>Affiliation</u>
Dr. Giacomo Basadonna	U. Massachusetts
Dr. Thomas Eggerman	NIDDK
Dr. Richard Furlanetto	JDRF
Dr. Osama Gabor	University of Tennessee
Dr. Ronald Gill	University of Colorado
Dr. Mark Hardy	Columbia University

Dr. Bernhard Hering  
Dr. Fouad Kandeel  
Dr. Richard Knazek  
Dr. Thalachallour Mohanakumar  
Dr. Ali Naji  
Dr. Joyce Niland, ABCC Director  
Dr. JoAnna Reems  
Dr. Camillo Ricordi  
Dr. Dan Saloman, Chairman  
Dr. Darin Weber (non-voting)  
Dr. Gordon Weir

University of Minnesota  
City of Hope/Beckman Research Institute  
NCRR  
Washington University  
University of Pennsylvania  
City of Hope/Beckman Research Institute  
Puget Sound Blood Center  
University of Miami  
Scripps Research Institute  
FDA  
Joslin Diabetes Center